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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/728,516  | 12/05/2003  | Tracee Eidenschink   | S63.2B-11293-US01   | 9041             |
| 499 7590 04/15/2011<br>VIDAS, ARRETT & STEINKRAUS, P.A.<br>SUITE 400, 6640 SHADY OAK ROAD<br>EDEN PRAIRIE, MN 55344 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| TYSON, MELANIE RUANO  |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 3773  |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/728,516

**Applicant(s)**

EIDENSCHINK ET AL.

**Examiner**

MELANIE TYSON

**Art Unit**

3773

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 February 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-14,35-38 and 55-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-14,35-38 and 55-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This action is in response to the applicant's amendment received 17 February 2011. The application is not in condition for allowance for the reasons set forth below. Claims 3, 15-34, and 39-54 remain cancelled.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 2, 4-14, 35-38, and 55-57 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bashiri (U.S. Publication No. 2003/0045923 A1).** Bashiri discloses a first serpentine band connected to a second serpentine band by at least one permanent connector strut (117) and at least one disengagable connector strut (114). Bashiri fails to disclose at

least a portion of the disengagable connector is made from a material having a higher corrosion potential than a material used to form the serpentine band. However, the applicant discloses in the specification that the disengagable connector struts may either be made of a material having a higher corrosion potential than a material used to form the serpentine band, or the disengagable struts may be formed of the same material of the stent but having a necked portion to allow for a rapid detachment without damage to other portions of the stent, thus indicating the embodiments are obvious variations and would perform equally well. Bashiri discloses the disengagable connector struts have a necked portion (120) and further discloses they may be constructed of the same or different materials as desired. Since it is well within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further construct at least a portion of Bashiri's disengagable connector struts from a material having a higher corrosion potential than the material used to form the serpentine band as a matter of design choice.

**Claims 1, 4-14, 35-38, and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (U.S. Patent No. 6,409,754 B1), Killion et al. (U.S. Patent No. 5,938,697), Bashiri, and Acosta et al. (U.S. Patent No. 7,137,993).**

Smith discloses a stent (see entire document) comprising an at least partially self-expanding framework comprising a plurality of serpentine bands, adjacent bands connected by permanent connector struts extending from each valley of one band to

each peak of the second band (for example, see Figure 2). Smith fails to disclose at least one disengagable connector strut.

Killion discloses a stent (see entire document) and teaches that it is well known in the art to modify the structure of stents to obtain certain properties. For example, a desired radial force may be achieved by varying the number of connectors, in which an open cell provides for less support and more flexibility (for example, see column 3, lines 9-30). Bashiri discloses an at least partially self-expanding stent (see entire document) and teaches disengagable connector struts (114b). Bashiri teaches the disengagable connector struts prevent the stent from self-expanding to a full deployment diameter, yet upon intentional disengagement of the disengagable connector struts, the number of cells decreases to form an open cell geometry (for example, see Figure 8). Smith suggests the permanent connector struts constrain the self-expandable framework until intentionally deformed permanently (for example, via balloon expansion) and teaches an alternate embodiment in which the disclosed stent may alternatively have an open cell geometry in which some of the peaks and valleys of adjacent bands lack connectors (for example, see Figure 5). Given the teachings of Killion, Bashiri, and Smith, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute at least one of Smith's permanent connector strut with a disengagable connector strut. Doing so would provide the advantage of maintaining the stent restrained until proper positioning is determined and expansion is desired, yet further provide the advantage of added flexibility to the stent in its final expanded state. This enables the stent to be utilized in applications where flexibility is desired. Smith as

modified fails to disclose or suggest an electrical lead coupled to the disengagable struts to cause disengagement by electrolytic detachment.

Acosta discloses a plurality of bands that at least partially self-expand comprising disengagable struts (see entire document). Acosta teaches electrically coupling an electrical lead extending from the bands (for example, on the distal end of a movable sheath) to the disengagable struts to induce electrolytic detachment of the struts having reduced thickness portions (for example, see Figure 7), wherein corrosion reduces the mass of the metal framework (see column 6, lines 18-40 for details). The substitution of known elements (electrical leads for providing electrolytic detachment of a detachment connector of reduced thickness) for another (a means for exerting a mechanical force of a breakable detachment connector of reduced thickness as disclosed by Bashiri) would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution of the detachment means would have yielded predictable results, namely, providing a means for disengaging the disengagable connector strut allowing the self-expanding stent to assume its full final deployment diameter when desired.

With further respect to claims 4-6, the applicant discloses in the specification that the electrical lead may be provided near the distal end of a sheath/catheter, attached directly to the disengagable connector struts, or comprise a plurality of leads each attached directly to a disengagable connector strut, thus indicating the embodiments are obvious variations and would perform equally well. Since it is well within the general skill of a worker in the art to modify the position of the leads as desired or to duplicate the number of leads as desired on the basis of suitability for the intended use, it would have

been obvious to one having ordinary skill in the art at the time the invention was made to further modify the leads as recited as a matter of design choice.

With further respect to claim 12, the applicant has not disclosed that this configuration provides an advantage, is used for a particular purpose, or solves a stated problem, indicating the embodiments are obvious variations, and it appears the prior art configuration would perform equally well. Since one having ordinary skill in the art could have connected the disengagable struts to the bands at the necked portion of the disengagable struts and the applicant has not stated any benefit of doing so, it would have been obvious to one having ordinary skill in the art at the time the invention was made to connect the disengagable struts to the bands at the necked portion of the disengagable struts as a matter of design choice.

With further respect to claim 57, the applicant discloses in the specification that the disengagable connector struts may either be made of a material having a higher corrosion potential than a material used to form the serpentine band, or the disengagable struts may be formed of the same material of the stent but having a necked portion to allow for a rapid detachment without damage to other portions of the stent, thus indicating the embodiments are obvious variations and would perform equally well. Bashiri discloses the disengagable connector struts have a necked portion (120) and further discloses they may be constructed of the same or different materials as desired. Since it is well within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further

Art Unit: 3773

construct at least a portion of the disengagable connector struts from a material having a higher corrosion potential than the material used to form the serpentine band as a matter of design choice.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE TYSON whose e-mail is [melanie.tyson@uspto.gov](mailto:melanie.tyson@uspto.gov) and telephone number is (571)272-9062. The examiner can normally be reached on Monday through Thursday 8-7 (IFP).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Tyson/



Application/Control Number: 10/728,516

Page 8

Art Unit: 3773

Primary Examiner, Art Unit 3773

April 13, 2011